

U.S. Food and Drug Administration

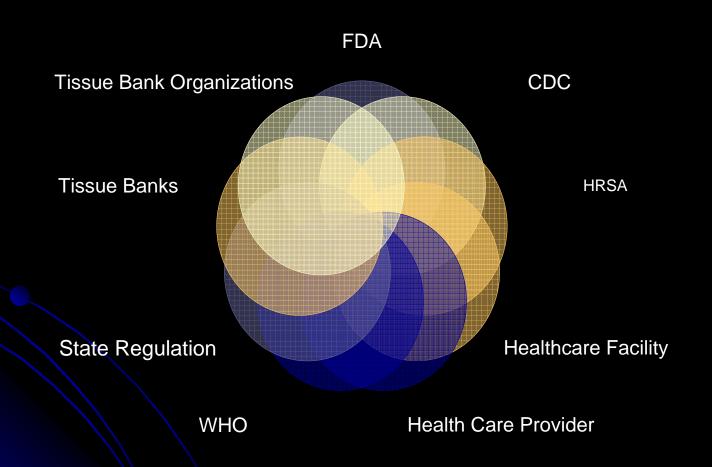


CENTER FOR BIOLOGICS EVALUATION AND RESEARCH

FDA and Tissue Regulation

Celia Witten, Ph.D., M.D.
Office Director, OCTGT, CBER, FDA
World Health Organization
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PATIENT SAFETY: EVERYONE'S GOAL



Outline

- Development of FDA Regulations and Guidance
- Working with Professional Organizations

LEGAL FRAMEWORK

Constitution

Statutes

Regulations

Guidance

STATUTES

- Public Health Service Act
 - -licensing provisions
 - -prevent communicable disease
- Federal Food, Drug and Cosmetic Act
- Other Statutes
 - -e.g. Administrative Procedure Act
 - Federal Advisory Committee Act

RULEMAKING AND POLICY: BASIS FOR REGULATORY DECISIONS

- Rule-" an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy"
- Has binding effect
- We create rules under statutory authorities (PHS Act and FDC Act)

GOOD GUIDANCE PRACTICES

(Title 21 Code of Federal Regulations (CFR) 10.115(a))

- GGP's are FDA's policies and procedures for developing, issuing, and using guidance documents
- Purpose-to make our procedures clear to public
- Regulated persons may chose an alternative approach that complies with laws and regulations

GOOD GUIDANCE PRACTICES

What is a Guidance Document? (21 CFR 10.115(b))

- A document prepared for FDA Staff, applicants/sponsors, and public that:
 - Describes FDA's interpretation of or policy on a regulatory issue; or
 - Relates to
 - The design, production, labeling, promotion, manufacturing, and testing of regulated products;
 - The processing, content, and evaluation or approval of submissions; and
 - Inspection and enforcement policies

Tissue Rules

 21 CFR Part 1270 - Human Tissue Intended for Transplantation

 21 CFR Part 1271- Human Cells, Tissues, and Cellular and Tissue-Based Products

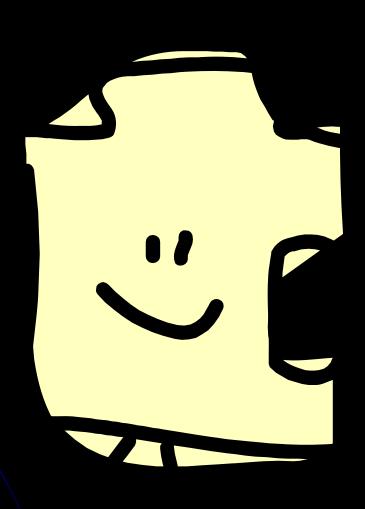
TISSUE GUIDANCE

- Guidance for Industry: MedWatch Form FDA 3500A: Mandatory Reporting of Adverse Reactions Related to Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/P's) – 11/30/2005
- Guidance for Industry: Recommendations for Obtaining a Labeling Claim for Communicable Disease Donor Screening Tests Using Cadaveric Blood Specimens from Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/P's) 11/12/2004
- Guidance for Industry: Validation of Procedures for Processing of Human Tissues Intended for Transplantation 3/8/2002

Tissue Guidance, cont'd

- Draft Guidance for Industry: Eligibility
 Determination for Donors of Human Cells,
 Tissues, and Cellular and Tissue-Based
 Products (HCT/Ps) 5/20/2004
- Draft Guidance for Industry: Preventive
 Measures to Reduce the Possible Risk of
 Transmission of Creutzfeldt-Jakob Disease
 (CJD) and Variant Creutzfeldt-Jakob Disease
 (vCJD) by Human Cells, Tissues, and Cellular
 and Tissue-Based Products (HCT/Ps) 6/14/2002

FDA is only one piece of the puzzle...



FDA / PROFESSIONAL ORGANIZATIONS

- Public input and dialogue on FDA regulations and guidance
- Professional standards
 - -Can be referred in a guidance
 - -How to comply with regulations
 - Areas not addressed by regulations or guidance

FDA/Professional Organizations: Communication

- Liaison Meetings
- Dissemination of FDA Policy
- Communication by industry of issues of concern
- Educational Programs
- Public workshops
- Participation at Public Advisory Committee Meetings

EXAMPLES

- EBAA/AATB Q's and A's on GTP's
- FDA liaison membership on committees (AATB Standards Committee, Medical Advisory Committee, Reproductive Council, EBAA Medical Advisory Committee)
- Participation in District Office Inspectors Training
- ISCT/FDA workshop on Somatic Cell Therapy

Examples, continued

- Workshop participation (examples)
 - Human Bone Allograft: Manipulation and Homologous Use in Spine and Other Orthopedic Reconstruction and Repair (8/2000)
 - Unrelated Allogeneic Cord Blood Banking and Transplantation Forum (8/2000)
- FDA Liaison to Unified Donor History Questionnaire Task Group



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CONTACT INFORMATION

Celia Witten, PH.D., M.D.
Office Director, OCTGT
CBER/FDA
1401 Rockville Pike (HFM 700)
Suite 200N
Rockville, MD 20852-1448

Celia.witten@fda.hhs.gov 301-827-5102